Application No.: 10/658,219 Docket No.: 559662000102

## **CLAIM AMENDMENTS**

## 1-19. (canceled)

- 20. (currently amended): A vial containing a [[dry]] dried native Factor VIII composition comprising a Factor VIII-stabilizing amount of trehalose and no albumin, the composition being
  - (a) stable without refrigeration, and
- (b) suitable for reconstitution with water or with an aqueous solution for administration to a hemophilic patient by injection.
- 21. (previously presented): The composition of claim 20, containing 0.15 to 2.5 mg trehalose per unit of Factor VIII.
- 22. (previously presented): The composition of claim 20, wherein said native Factor VIII is recombinant.
- 23. (previously presented): The composition of claim 20, containing 1.0 to 1.5 mg Ca<sup>2+</sup> per unit of Factor VIII.
- 24. (previously presented): The composition of claim 20, wherein the composition comprises salt and the molar ratio of trehalose to the salt is above 1:1.
- 25. (previously presented): The composition of claim 24, containing more than 2.5 moles trehalose per mole of salt.
- 26. (previously presented): The composition of claim 25, containing more than 10 moles trehalose per mole of salt.

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27. (currently amended): A process of preparing a dry for preparing the dried native Factor VIII composition defined in claim 20 which comprising a Factor VIII stabilizing amount of trehalose and no albumin, the composition being

- (a) stable without refrigeration, and
- (b) suitable for reconstitution with water or with an aqueous solution for administration to a hemophilic patient,

the process comprising comprises drying a solution of native Factor VIII and trehalose in the absence of albumin.

- 28. (previously presented): The process of claim 27, wherein the drying is done at a temperature of no greater than 10°C.
  - 29. (previously presented): The process of claim 28, wherein the drying is freeze-drying.
- 30. (previously presented): The process of claim 27, wherein an aliquot of the solution is placed in a vial and is freeze-dried.
- 31. (currently amended): [[The]] A method for preparing a Factor VIII therapeutic composition for administration to a patient wherein the method comprises reconstituting the composition [[ef]] defined in claim 20 to obtain a solution that is suitable for injection.
- 32. (previously presented): The method of claim 31, wherein the reconstituting with water.
- 33. (previously presented): The method of claim 31, wherein the reconstituting is with saline.

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